UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STEVEN STREZSAK, et al.,

Plaintiffs,

v.

ARDELYX INC., et al.,

Defendants.

Case No. 21-cv-05868-HSG

ORDER GRANTING MOTION TO DISMISS

Re: Dkt. No. 101

Pending before the Court is a motion to dismiss Lead Plaintiff's putative securities class action filed by Defendants Ardelyx Inc., Mike Raab, Justin Renz, and David Rosenbaum ("Defendants"). Dkt. No. 101. The Court finds the matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b). For the reasons below, the Court **GRANTS** the motion to dismiss **WITH LEAVE TO AMEND**.

I. BACKGROUND

Ardelyx is a biopharmaceutical company that began developing tenapanor around 2009 as a treatment for irritable bowel syndrome. Dkt. No. 97 ¶ 26 (Second Amended Complaint ("SAC")). Several years later, Ardelyx pivoted to seeking FDA approval of tenapanor for the treatment of hyperphosphatemia, a condition resulting from high levels of phosphate in the blood. *Id.* ¶ 27.

Although there are existing FDA-approved treatments for hyperphosphatemia, tenapanor was a first-in-class therapy due to its novel mechanism of action. *Id.* ¶ 28. Ardelyx conducted three Phase 3 clinical trials of tenapanor as a treatment for hyperphosphatemia using a "surrogate" endpoint—the level of serum phosphates measured in trial participants—rather than a particular clinical outcome, such as reduced morbidity or mortality. *Id.* ¶¶ 31, 36.

In November 2017, the FDA provided Defendants with feedback in connection with their first study, noting that "[i]f the size of the effect of tenapanor on serum phosphates [was] significantly smaller than the size of the effect of currently approved phosphate binders," Defendants would "need to address the clinical relevance of the effect of [tenapanor] on serum phosphates." *Id.* ¶ 44. In December 2018, the FDA issued an "Advice Letter" in response to Defendants' labeling inquiry, stating that "the results could be described in labeling" only if "the trial is well-conducted and the size of the treatment effect [was] clinically relevant." *Id.* ¶ 45. During a March 2020 Meeting, the FDA raised concerns about Ardelyx's New Drug Application (NDA) and the NDA's supporting clinical data. *Id.* ¶ 40. Specifically, the FDA warned Ardelyx that "while it ha[d] accepted serum phosphorus as a surrogate endpoint" in evaluating whether to approve other drugs intended to treat hyperphosphatemia, "a treatment effect of any magnitude is not considered sufficient to support approval." *Id.* ¶ 41. The FDA instructed that Ardelyx needed to "address the clinical relevance of the magnitude of the treatment effect observed in [its] development program in [its] NDA submissions," and conveyed that it was "interested in the evidence supporting the conclusion that the magnitude of the treatment effect" of tenapanor on hyperphosphatemia "is clinically relevant, as opposed to 'expert opinion.'" *Id.* The FDA also told Defendants that "showing a marked treatment effect in patients with more marked elevations in [serum phosphorus] level at baseline could be compelling." *Id.*

On July 19, 2021, Defendants disclosed that the FDA had "identified deficiencies" in the NDA that precluded the application from moving forward. *Id.* ¶¶ 88–89. Ardelyx's share price dropped 74% in trading the following day. *Id.* ¶ 90. The "key" deficiencies identified by the FDA related to "the size of the treatment effect [of tenapanor] and its clinical relevance" as shown in the NDA's supporting data. *Id.* ¶ 89. On July 29, 2021, Defendants further disclosed that the FDA determined that although "the submitted data provide[d] substantial evidence that tenapanor [was] effective in reducing serum phosphorous in CKD patients on dialysis," "the magnitude of the treatment effect" was "small and of unclear clinical significance." *Id.* ¶ 92. The FDA further noted that Defendants would have to demonstrate a "clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia" in

the relevant patient population. *Id.*

Plaintiff alleges that prior to the July 19, 2021 disclosure, Defendants knew that the FDA had significant concerns about the magnitude of the treatment effect of tenapanor and whether it was clinically relevant, but nevertheless made statements expressing confidence in their dialogue with the FDA, their trial data, and in tenapor's eventual approval. Plaintiff alleges that these statements were materially misleading because they omitted the apparent concerns raised by the FDA.

Plaintiff brings this putative class action on behalf of of individuals who purchased or otherwise acquired Ardelyx securities between March 6, 2020 and July 19, 2021, inclusive ("Class Period"), and who were damaged as a result of Defendants' violations of the Exchange Act ("Class"). *Id.* ¶ 1.

II. LEGAL STANDARD

A. Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when a plaintiff pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, Courts do not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Secs. Litig.*, 536

F.3d 1049, 1055 (9th Cir. 2008).

B. Heightened Pleading Standard

Section 10(b) of the Securities Exchange Act of 1934 provides that it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered . . . any manipulative or deceptive device or contrivance . . . ." 15 U.S.C. § 78j(b). Under this section, the SEC promulgated Rule 10b-5, which makes it unlawful, among other things, "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). To prevail on a claim for violations of either Section 10(b) or Rule 10b-5, a plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). At the pleading stage, a complaint alleging claims under Section 10(b) and Rule 10b-5 must not only meet the requirements of Federal Rule of Civil Procedure 8, but also satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). Under Rule 9(b), claims alleging fraud are subject to a heightened pleading requirement, which requires that a party "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Additionally, all private securities fraud complaints are subject to the "more exacting pleading requirements" of the PSLRA, which require that the complaint plead with particularity both falsity and scienter. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009).

III. REQUEST FOR JUDICIAL NOTICE

Defendants request that the Court incorporate by reference or take judicial notice of exhibits A–S (Dkt. Nos. 101-2–20) from the Declaration of Daniel R. Gherardi (Dkt. No. 101-1).

A. Incorporation by Reference

In the Ninth Circuit, incorporation by reference is a doctrine that "treats certain documents as though they are part of the complaint itself." *Khoja v. Orexigen Therapeutics*, 899 F.3d 988, 1002 (9th Cir. 2018). A document may be incorporated by reference into a complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). "Once a document is deemed incorporated by reference, the entire document is assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free to refer to any of its contents." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.10 (9th Cir. 2014) (internal quotation marks and citation omitted). Although the truth of an incorporated document may not be considered *solely* to dispute *well-pled* facts, the Court need not accept as true conclusory allegations that are contradicted by documents referenced in the complaint. *See In re Eventbrite, Inc. Securities Litigation*, 2020 WL 2042078, at *7 (N.D. Cal. Apr. 28, 2020).

Defendants seek to incorporate exhibits A–D, F–J, L, and N–S into the SAC. Plaintiff does not contest that exhibits A–D, F–I, and N–S are incorporated by reference. Dkt. No. 106 at 1. n.1. The Court agrees that these documents either form the basis of the plaintiff's claim or are referred to extensively in the SAC. *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). The Court grants the request to incorporate these documents by reference.

Plaintiff argues that exhibits J and L should not be incorporated by reference. Exhibit J is a press release issued by Ardelyx on December 29, 2022. Exhibit L is a press release issued by Ardelyx on November 16, 2022. The SAC does not specifically refer to the press releases, and the SAC does not allege that their contents materially speak to an element of Plaintiff's claims. The Court declines to incorporate these documents by reference.

B. Judicial Notice

Under Federal Rule of Evidence 201, a court may take judicial notice of a fact "not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Accordingly, a court may take "judicial notice of matters of public record," but "cannot take judicial notice of disputed facts

contained in such public records." *Khoja*, 899 F.3d at 999 (citation and quotations omitted). The Ninth Circuit has clarified that if a court takes judicial notice of a document, it must specify what facts it judicially noticed from the document. *Id.* at 999.

Defendants contend that each of the exhibits is properly considered by the Court pursuant to the doctrine of judicial notice. The Court agrees. As to exhibits A–D, F–I, and N–S, which the Court incorporated by reference into the SAC, the Court also finds these documents are subject to consideration under the doctrine of judicial notice.

Exhibit A (2020 Form 10-K), Exhibit N (8/6/20 Form 10-Q), and Exhibit O (5/6/21 Form 10-Q) are documents that Ardelyx publicly filed with the SEC that are available to the public through the SEC's website. These documents are not subject to reasonable dispute, and the "accuracy" of these publicly filed SEC documents "cannot reasonably be questioned." *Waterford Twp. Police v. Mattel, Inc.*, 321 F. Supp. 3d 1133, 1143 (C.D. Cal. 2018) (granting judicial notice of transcripts of earnings calls and excerpts of SEC filings); *In re Aqua Metals, Inc. Sec. Litig.*, 2019 WL 3817849, at *5 (N.D. Cal. Aug. 14, 2019) (taking judicial notice of SEC filings). Exhibit P (Raab Forms 4) is a compilation of Defendant Michael Raab's Forms 4. Courts may take judicial notice of SEC Forms 4 to prove that stock sales were made pursuant to a Rule 10b5–1 trading plan. *See Wochos v. Tesla, Inc.*, 2018 WL 4076437, at *2 (N.D. Cal. Aug. 27, 2018) (SEC filings subject to judicial notice); *see also Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting that SEC filings are subject to judicial notice).

Exhibit B (9/15/20 Press Release), Exhibit D (8/6/20 Press Release), Exhibit I (4/29/21 Press Release), Exhibit J (12/29/22 Press Release), Exhibit K (5/3/23 Press Release), Exhibit L (11/16/22 Press Release), Exhibit Q (7/19/21 Press Release), and Exhibit R (7/29/21 Press Release) are press releases publicly available on Ardelyx's website and are not subject to reasonable dispute. As such, they are subject to judicial notice. *Aqua Metals*, 2019 WL 3817849, at *5 (taking judicial notice of press releases); *Sgarlata v. PayPal Holdings, Inc.*, 2018 WL 6592771, at *6 (N.D. Cal. Dec. 13, 2018) (same).

Exhibit C (FDA Briefing Document), Exhibit E (FDA Surrogate Endpoint Resources for Drug and Biologic Development), Exhibit F (FDA Table of Surrogate Endpoints) and Exhibit M

(FDA Website Describing NDAs) are documents that are publicly available on the FDA's website and not subject to reasonable dispute. As such, they are subject to judicial notice. *See Lake v. Zogenix, Inc.*, 2020 WL 3820424 at *5 (taking notice of publicly available FDA guidance document); *Gustavson v. Mars, Inc.*, 2014 WL 2604774, at *3 n.1 (N.D. Cal. June 10, 2014) (taking judicial notice of FDA letters and press releases because "these documents are readily available on a government agency website").

Exhibit G (11/17/20 Jefferies Conference Transcript), Exhibit H (2/24/21 SVB Leerink Conference Transcript) and Exhibit S (11/18/21 Jefferies Conference Transcript) are transcripts of investor conferences. These documents are not subject to reasonable dispute and can be accurately and readily determined through public websites. Courts routinely take judicial notice of transcripts of calls with and presentations to investors in securities cases. *See In re Splunk Inc. Sec. Litig.*, 592 F.Supp.3d 919, 929 (N.D. Cal. 2022) (taking judicial notice of transcripts of calls with and presentations to analysts and investors); *Forsyth v. HP Inc.*, 2021 WL 1391501, at *4–5 (N.D. Cal. Apr. 13, 2021) (taking judicial notice of conference call transcripts).

Accordingly, the Court takes judicial notice of all the documents described above for the purpose of considering what was disclosed to the market. In doing so, the Court does not assume the truth of any of the facts asserted. *Wochos*, 2018 WL 4076437, at *2.

IV. DISCUSSION

A. Section 10(b) and Rule 10b-5

i. Falsity

a. Legal Standard

Defendants contend that the statements challenged in the SAC are not materially false or misleading. "Falsity is alleged when a plaintiff points to [the] defendant's statements that directly contradict what the defendant knew at that time." *Khoja*, 899 at 1008. "In setting forth the reasons why they contend that each challenged statement is misleading, securities plaintiffs may rely either on an affirmative misrepresentation theory or an omission theory." *Wochos*, 985 F.3d at 1188 (citing 17 C.F.R. § 240.10b–5(b)). "Under Rule 10b–5, an affirmative misrepresentation is an 'untrue statement of a material fact.'" *Id.* "A statement is misleading if it would give a

reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Retail Wholesale & Dep't Store Union Local 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir. 2017) (quotations and alterations omitted). "To be misleading, a statement must be 'capable of objective verification.'" *Id.* (internal citation removed). However, even "general statements of optimism, when taken in context," may be misleading "when those statements address specific aspects of a company's operation that the speaker knows to be performing poorly." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1143 (9th Cir. 2017).

"Even if a statement is not false, it may be misleading if it omits material information." *Khoja*, 899 F.3d at 1008–09. "An omission is material when there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *Irving Firemen's Relief & Ret. Fund v. Uber Tech.*, 398 F. Supp. 3d 549, 555–56 (N.D. Cal. 2019) (citation omitted).

b. Challenged Statements

Plaintiff alleges numerous false and misleading statements by Defendants. First, Plaintiff challenges Defendants' description of its interactions with the FDA. For example, Defendants stated that the interactions with the FDA "hav[e] gone exceedingly well," that "there's been nothing [untoward] and anything that causes us concern" from the FDA, and that Defendants had only "standard" interactions with the FDA. SAC ¶¶ 6, 74. Second, Plaintiff challenges Defendants' description of the "successful" clinical trials. For example, Defendants characterized these trials as producing "comprehensive," "extensive," "significant," and "robust" and "clinically relevant" data. *See, e.g.*, *id.* ¶¶ 59, 61, 67, 69, 70, 73–74, 77, 79, 82, 84, 86. Third, Plaintiff challenges statements expressing confidence in tenapor's "potential to transform the treatment landscape for patients" and statements expressing an "expectation" of FDA approval. *See, e.g.*, *id.* ¶¶ 55, 69. Plaintiff alleges that based on the FDA's stated concerns Defendants knew they did not have the data required for approval and made knowingly false representations to the contrary.

c. Analysis

The Court finds that the statements described above constitute opinions because "they

inherently reflect the speaker's assessment of and judgment about the underlying circumstances." *Markette v. XOMA Corp.*, No. 15-CV-03425-HSG, 2017 WL 4310759, at *4 (N.D. Cal. Sept. 28, 2017). To plead the falsity of an opinion, a plaintiff "must allege both that 'the speaker did not hold the belief she professed' and that the belief is objectively untrue." *City of Dearborn Heights Act 345 Police. & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017) (internal citation removed). As the Supreme Court explained in *Omnicare*, "a statement of opinion is not misleading just because external facts show the opinion to be incorrect." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 186 (2015). "[W]hether an omission makes an expression of opinion misleading always depends on context." *Id.* at 190. Investors take into account "the customs and practices of the relevant industry," "[s]o an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as appropriate, in a broader frame." *Id.*

Here, the FDA indicated that Defendants would need to demonstrate clinical relevance and provide a justification for approval given that tenapor showed a smaller effect size than seen in already approved agents. Based on these statements, Plaintiff asks the Court to infer that the FDA had expressed that the trial evidence presented would not be sufficient for approval. Plaintiff would have the Court further infer that the FDA's statements convinced Defendants that the tenapor review process was not actually proceeding in an ordinary manner, that the clinical data was not robust or clinically relevant, and that approval was thus in jeopardy. Plaintiff does not provide the Court with sufficient alleged facts to support these inferences. As such, Plaintiff fails to allege that Defendants did not hold the optimistic beliefs professed or that those beliefs were objectively untrue. *See Pardi v. Tricida*, 2024 WL 1056013, at *7 (N.D. Cal. Mar. 11, 2024) ("FDA's expression of its view that the results likely would not be applicable to the U.S. population does not show that [defendant's] confidence in the likelihood of approval was necessarily objectively false or not honestly held.").

Moreover, Defendants had "no legal obligation to loop the public into each detail of every communication with the FDA." *In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) (quoting *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017)); *see*

also Tongue v. Sanofi, 816 F.3d 199, 214 ("[N]o sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA.") Instead, such a duty to disclose arises in limited circumstances. For example, Defendants would have a duty to disclose the FDA's feedback if it contradicted Defendants' statements, presented risks that were "out of the ordinary," or implicated a "special challenge not of the kind normally confronted by pharmaceutical companies seeking FDA approval for their drugs." *Sanofi*, 816 F.3d at 212; *In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7. Here, during the Class Period the FDA did not express any doubts about approval or communicate facts to suggest that Defendants would need to overcome "special" hurdles to obtain approval. Nor do the FDA's statements contradict Defendants' statements concerning the sufficiency of the clinical trials. Even if the Court credits the inference that the FDA's statements cast doubt on the trial data, the FDA's statements at most constitute "contrary views" to Defendants' statements concerning the sufficiency of the data—communications that courts have not required similarly situated Defendants to disclose. *In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 ("Reasonable investors would expect that the company and the FDA would be engaged in a dialogue about the sufficiency of the clinical trials and that such dialogue inherently would include presentation of contrary views.") (citing *Sanofi*, 816 F.3d at 212 (no plausible allegation that FDA interim feedback conflicted with company's opinion about FDA approval timeline or that failure to disclose it made opinion misleading)); *see also In re Amylin Pharm., Inc. Sec. Litig.*, 2003 WL 21500525, at *6 (S.D. Cal. May 1, 2003) (while company seeking FDA approval of a new drug is not obligated to disclose every issue raised by FDA, defendants were obligated to disclose significant concerns that rendered FDA approval seriously doubtful).

The Court is further persuaded by the fact that Defendants publicly disclosed many of these allegedly omitted facts. Specifically, Defendants cautioned investors that "[e]ven if we believe a clinical trial has demonstrated . . . efficacy . . . [that] data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval." Dkt. No. 101-2 at 25

(Ex. A, 2020 Form 10-K).[1] Defendants warned that success depended on whether tenapanor's "efficacy profile is satisfactory to the FDA," and that while tenapanor met its clinical trial endpoints "it may not be possible or practicable to demonstrate . . . certain of the benefits we believe tenapanor possesses." *Id.* at 20, 25. And Defendants cautioned that because tenapor was a first-in-class drug, "there is a higher likelihood that approval may not be attained as compared to a class of drugs with approved products." *Id.* at 20. As such, even if Defendants had a duty to disclose the FDA's statements, Defendants specifically disclosed the thrust of the concerns Plaintiff asks the Court to infer from the FDA statements at issue.

Plaintiff's citations to the contrary do not support a different result. In *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 708 (9th Cir. 2016), defendant stated that "'all the . . . studies that [had] been completed' supported [defendant's] case for approval" even though the studies were "*the* sticking point with the FDA." During the process, the FDA made "highly unusual" and "out-of-process" bi-monthly demands for information. *Id.* at 707.[2] Here, the FDA expressed no explicit concerns about the trial or its likelihood of approval. Nor does Plaintiff allege how or why the FDA feedback was "out of process." Plaintiff argues that the feedback at the March 2020 pre-NDA meeting was unusual because such meetings usually involve administrative rather than substantive matters, but Plaintiff also alleges that the "ultimate" objective of Pre-NDA meetings is to determine whether outstanding issues require additional data or studies. SAC ¶ 8. As such, even if the Court construes the FDA's feedback as flagging "outstanding issues" requiring additional data, the FDA's choice to raise such concerns does not appear, as alleged, to be "out of process," especially compared to the affirmative demands for information in *Schueneman*. Plaintiff also cites *Homyk v. Chemocentryx*, where the court held defendants' expressions of confidence were misleading because the FDA specifically and repeatedly warned defendants of numerous deficiencies in their trial design. 2023 WL 3579440 at *7–11 (N.D. Cal. Feb. 23, 2023).

[1] The Court incorporated Exhibit A into the Complaint by reference.
[2] The Court notes that *Schueneman* formally addressed scienter rather than falsity. *Id.* at 707. The court held that plaintiff adequately pled scienter given the allegations that the company reported favorable results on the study but concealed strong indications that the drug caused cancer in rats. *Id.*

However, despite these glaring warnings, the court found that plaintiffs failed to plead facts to contradict Defendants' statements that the "review process in our opinion is going in a very straightforward, routine manner," and that there was "nothing extraordinary to report." *Id.* at *15.

Ultimately, Defendants had a years-long iterative dialogue with the FDA, during which the agency unsurprisingly expressed its outlook on the general guidelines for tenapor's approval and explained its expectation that Defendants would need to provide a justification if their application fell short of those guidelines. Defendants were free to express optimism in their application and the prospects for approval, and the feedback from the FDA did not render those expressions of optimism false. To the extent that feedback presented views contrary to those expressions of optimism, Defendants had no obligation to share every opinion raised by the FDA absent more compelling circumstances. In any event, Defendants themselves disclosed the risks involved with first-in-class drug applications, including the risk that the FDA may interpret the clinical data as insufficient for approval. As such, Plaintiff does not plausibly allege that the opinion statements at issue were false or misleading by omission under the demanding standard set by the PSLRA.[3]

ii. Scienter

The PSLRA requires that a plaintiff specify each statement alleged to have been misleading and the reason or reasons why the statement is misleading, and show that the

[3] The Court also notes that nearly all the challenged statements amount to nonactionable statements of corporate optimism. Courts routinely dismiss challenges to "highly subjective claims" that are not "specific, detailed factual assertions," including optimistic descriptions of clinical data and regulatory interactions. *Kipling v. Flex Ltd.*, 2020 WL 2793463, *13 (N.D. Cal. May 29, 2020); *see, e.g.*, *In re Atossa Genetics Inc. Sec. Litig.*¸ 868 F.3d 784, 799-800 (9th Cir. 2017) (finding statement that management was "reasonably confident" in FDA communications to be nonactionable puffery); *In re Arrowhead Pharms., Inc. Sec. Litig.*, 2017 WL 5635422, at *9 (C.D. Cal. Sept. 20, 2017) (statements such as a drug being "well tolerated with no serious adverse events" are "statements of optimism relating to how Defendant interpreted its study results" and are "non-actionable"); *Juniper Networks, Inc.*, 880 F. Supp. At 1064 (dismissing challenge to statements of confidence in "robust" product portfolio); *Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *11 (N.D. Cal. Sept. 27, 2012) (statements about drug's "'excellent' or 'compelling' risk/benefit profile" and "that the trials had shown 'remarkable' safety and efficacy" were nonactionable). Defendants' opinion that the trial data demonstrated "clinically relevant" outcomes does not appear to qualify as "highly subjective" corporate puffery, but that statement is nevertheless insufficiently alleged to be false or misleading for the reasons described above.

allegations "give rise to a strong inference that the defendant acted with the required state of mind." *See Schueneman*, 840 F.3d at 705. Thus, a plaintiff's burden "is to allege sufficiently particular facts to demonstrate a strong inference of scienter—a mental state that not only covers 'intent to deceive, manipulate, or defraud,' but also 'deliberate recklessness.'" *Id.* (internal citations omitted). The Ninth Circuit has defined "deliberate recklessness" as more than "mere recklessness or a motive to commit fraud." *Zucco*, 552 F.3d at 991. "[D]eliberate recklessness is 'an extreme departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Schueneman*, 840 F.3d at 705 (quoting *Zucco*, 552 F.3d at 991 (internal quotation marks omitted)). "A complaint will survive," the Supreme Court has instructed, "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). "All in all, though not impossible, this 'is not an easy standard to comply with—it was not intended to be—and plaintiffs must be held to it.'" *Schueneman*, 840 F.3d at 705 (quoting *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (per curiam)).

At the outset, the Court notes that it need not reach scienter because Plaintiff failed to plead that Defendants made any false or misleading statements. The following analysis provides guidance for any amendment of the complaint.

a. Direct Knowledge

Plaintiff alleges that Defendants told investors only positive information about the drug trials, tenapanor's efficacy, and their communications with the FDA while omitting any mention of the FDA's alleged concerns. Plaintiff contends that Defendants' knowledge of facts contrary to their representations to investors alone is sufficient to allege scienter.

However, Plaintiff has not adequately pled that Defendants' statements were false or misleading in the first place. As noted, the FDA communications did not convey the type of serious and express concerns that could establish the knowing falsity of the challenged statements of opinion. Simply failing to "divulge the details of interim 'regulatory back-and-forth' with the

FDA . . . alone cannot support an inference of scienter." *See In re Dynavax Sec. Litig.*, at *7 (citing *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 59 (1st Cir. 2018)); *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008) (no scienter where FDA briefing document "d[id] not demonstrate that there were certain dangers, known all along to defendants, which would prevent the approval and marketing of [the drug]"); *Rigel*, 697 F.3d at 883 n.10 (affirming dismissal where "the omitted information did not contradict, or render misleading, the original reports of the top-line results"). Thus, Plaintiff has not adequately pled facts to infer that Defendants knew their statements to be false or misleading. *See Juniper Networks, Inc.*, 880 F. at 1068.

b. Suspicious Individual Trading Activity

Plaintiff also points to Defendant Raab's allegedly suspicious share trading activity as evidence of scienter. Raab sold 29,698 shares of Ardelyx common stock in 2019, but sold 198,516 shares worth roughly $1.25 million during the fifteen-month Class Period. SAC ¶ 103; Dkt. No. 101-17 (Ex. P, Raab Forms 4). Plaintiff contends in his briefing that Defendant Raab entered into a Rule 10b5-1 plan in December 2019 after completion of one of the Phase 3 trials, setting the sales to occur prior to the end of tenapor's NDA review period. *See* Dkt. No. 105 at 23–24. Pursuant to this 10b5-1 plan, Plaintiff contends that Raab concealed the "negative information" of the FDA's concerns to artificially inflate the stock for his planned sale. *See id*.

"To evaluate suspiciousness of stock sales, [courts] consider, inter alia, three factors: (1) the amount and percentage of shares sold; (2) timing of the sales; and (3) consistency with prior trading history." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 2012 WL 1868874, at *22 (N.D. Cal. May 22, 2012), *aff'd*, 759 F.3d 1051 (9th Cir. 2014) (quoting *Nursing Home Pension Fund, Loc. 144 v. Oracle Corp.*, 380 F.3d 1226, 1232 (9th Cir. 2004). While insider trading may serve as circumstantial evidence of scienter, it "is suspicious only when it is dramatically out of line with prior trading practices at times calculated to maximize personal benefit from undisclosed inside information." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063–64 (9th Cir. 2014) (internal citations omitted).

In the first instance, Plaintiff did not plead the theory articulated above in the SAC.

Instead, the SAC simply details the sales and expects the Court to infer the connection between Raab's sales and the possession of non-public information. Such allegations are not sufficient. *In re LeapFrog Ents., Inc. Sec. Litig.*, 527 F. Supp. 2d 1033, 1052 (N.D. Cal. 2007) (rejecting scienter allegations because "plaintiffs make no attempt to plead how the timing of any specific sale by any specific defendant is linked to intentional misrepresentations or omissions or gives rise to an inference of scienter as to specific misstatements or omissions").

Regardless, Plaintiff did not carry his burden. Despite the notable more than sixfold increase in shares sold during the Class Period, an allegation that only one Defendant displayed unusual stock trades during the Class Period generally cannot support a "strong inference" of scienter absent some corroborating evidence. *Juniper Networks, Inc.*, 880 F. Supp. at 1069; *Metzler*, 540 F.3d at 1067 ("We typically require larger sales amounts-and corroborative sales by other defendants—to allow insider trading to support scienter.") Such corroborating evidence is absent here. Moreover, the SAC does not contain any particularized allegations concerning what percentage of his holdings Raab sold. *See Intuitive Surgical, Inc.* 2012 WL 1868874, at *22 ("inside trading becomes suspicious only when considered in comparison to the defendant's overall portfolio and trading practices"); *c.f. Aqua Metals*, 2020 WL 6710096, at *16 (no scienter where the complaint "fails to include any allegations concerning the percentage of their holdings they sold").[4]

c. Core Operations Theory

Plaintiffs also rely on the core operations theory, which presumes that "'corporate officers have knowledge of the critical core operations of their companies.'" *Prodanova v. H.C. Wainwright & Co., LLC*, 993 F.3d 1097, 1111 (9th Cir. 2021) (internal citation removed). As the Ninth Circuit explained in *Prodanova*,

[4] Defendants contend that these sales were made automatically pursuant to Rule 10b5-1 trading plans or were conducted to "cover" taxes implicated by new equity compensation grants. Dkt. No. 101 at 25–26. Plaintiff did not allege these facts or clearly concede them as true. Dkt. No. 105 at 23–24. Nor does the SEC filing cited by Defendants establish these facts. *See* Ex. P (compiling Forms 4). Accordingly, the Court cannot consider these facts for the purposes of this Rule 12(b)(6) motion.

> There are three circumstances under which core operations allegations can support a strong inference of scienter: (1) when they, along with other allegations, support a cogent and compelling inference of scienter; (2) when they are themselves particular and suggest that the defendants had actual access to the disputed information, and (3) in the "rare circumstances" when they are not particularized, but "the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter." Id. (citation omitted). "Proof under this theory is not easy." Intuitive Surgical, 759 F.3d at 1062. Plaintiffs "must provide either specific admissions by the executives that they were involved in the details of a company's operations or witness statements that the executives were specifically involved in producing the false reports."

Id. at 1111. The SAC does not plead particularized facts sufficient to support any of the three formulations of the core operations theory. Plaintiff simply alleges that because tenapanor was "important" to Ardelyx the Court should assume that all Defendants knew every possible adverse fact about it. SAC ¶ 102. This is not sufficient. *See Pardi*, 2022 WL 3018144, at *15 (argument that the "the day-to-day operations at [the company] . . . focused solely on shepherding [the drug] through clinical trials and FDA approval to commercialization" insufficient to establish scienter through the core operations theory); *In re AnaptysBio, Inc. Sec. Litig.*, 2021 WL 4267413 at *14 (S.D. Cal. Sept. 20, 2021) (rejecting plaintiffs' core operations theory based on the importance of the company's drug).

d. Holistic Analysis

"While it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference . . . allegations must be considered collectively; the significance that can be ascribed to an allegation of motive, or lack thereof, depends on the entirety of the complaint." *Juniper Networks, Inc.*, 880 F. at 1069 (N.D. Cal. 2012) (quoting *Tellabs*, 551 U.S. at 325). Plaintiff contends that Defendants expended resources conducting clinical trials despite purportedly knowing that the FDA would reject the application, all to keep Ardelyx's stock price inflated in the short-term. Without stronger allegations relating to suspicious trading based on that artificial inflation, this theory is unconvincing. *See Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020) (finding scienter insufficiently pled where plaintiff failed to establish a motive, including through insider trading, and "asked [the court] to

accept the theory that defendants were promising FDA approval for a medical device application they knew was 'unapprovable,' misleading the market all the way up to the point that defendants were 'unable to avoid the inevitable.'"); *Immanuel Lake v. Zogenix, Inc.*, 2020 WL 3820424, at *11 (N.D. Cal. Jan. 27, 2020) (finding scienter insufficiently pled where "[p]laintiffs have no answer to defendants' benign explanation . . . that '[defendant] had every incentive to get it right the first time, and to put [its drug] on the path to approval'"); *Jun Shi v. Ampio Pharms., Inc.*, 2020 WL 5092910, at *5 (C.D. Cal. June 19, 2020) ("[t]he idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason[.]"). Further undercutting this theory of concealment and artificial inflation, Defendants explicitly warned investors about the heightened risks of non-approval given tenapor's novel mechanism of action. Ultimately, the inferences the Court could draw from the limited allegations relating to scienter are not as compelling as competing innocent inferences. The more convincing theory is that Plaintiff believed that its trials were successful, that its interactions with the FDA were straightforward, and that the drug likely would be approved, and expressed that optimism to investors. Accordingly, Plaintiff fails to plead scienter.

iii. Loss Causation

"[T]o satisfy the loss causation requirement, the plaintiff must show that the revelation of [the relevant] misrepresentation or omission was a substantial factor in causing a decline in the security's price, thus creating an actual economic loss for the plaintiff." *Nuveen Mun. High Income Opportunity Fund v. City of Alameda, Cal.*, 730 F.3d 1111, 1119 (9th Cir. 2013) (quoting *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 425–26 (3d Cir. 2007)). This "burden of pleading loss causation is typically satisfied by allegations that the defendant revealed the truth through 'corrective disclosures' which 'caused the company's stock price to drop and investors to lose money.'" *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016) (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 264 (2014)). However, this is not the only way to meet the pleading burden. Instead, "loss causation is simply a variant of proximate cause," and "the ultimate issue is whether the defendant's misstatement, as opposed to some other fact, foreseeably

caused the plaintiff's loss." *Id.* at 1210; *see also Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) ("To prove loss causation, plaintiffs need only show a 'causal connection' between the fraud and the loss . . . by tracing the loss back to 'the very facts about which the defendant lied.'") (internal citations omitted).

Here, the Court has found that Defendants made no false or misleading statements. As such, the alleged corrective disclosure did not correct any actionable misstatements, and Plaintiff fails to establish that any misleading statement was the proximate cause of the July 20, 2019 stock drop. *See Loos v. Immersion Corp.*, 762 F.3d 880, 887–88 (9th Cir. 2014) (allegations regarding the company's "disappointing" financial results were insufficient to plead loss causation where the results "[did] not tend to suggest that the company had engaged" in fraud, but rather, were "merely indicative of poor financial health" and the disclosures "simply reveal[ed] that [the company] failed to meet its revenue goals").

B. Section 20(a) Claim

Because Plaintiff does not adequately plead a Section 10(b) claim, his Section 20(a) claim fails. *See Lake v. Zogenix, Inc.*, 2020 WL 3820424, at *13 (N.D. Cal. Jan. 27, 2020).

V. CONCLUSION

For the reasons stated above, the Court **GRANTS** the motion to dismiss **WITH LEAVE TO AMEND.**

Since the Court cannot conclude that amendment would be futile, Plaintiff may file an amended complaint within 21 days of the date of this order. When preparing an amended complaint, Plaintiff is further ordered to prepare a statement-by-statement chart of the information required by 15 U.S.C. § 78u-4(b)(1) and (2) that specifically identifies: (A) each statement or action alleged to have been false or misleading, (B) the reasons the statement or action was false, misleading, or deceptive when made, and (C) if an allegation regarding the statement or omission is made on information and belief, all facts on which the belief is formed. The chart should clearly identify which statements or omissions are attributable to which Defendants, and include a detailed statement of the facts giving rise to a strong inference that each Defendant acted with the required state of mind. Plaintiff should also summarize their allegations regarding what each

Defendant knew with regard to the statement or omission, and when they knew it. Such a chart should be included within any amended complaint or attached to any amended complaint. For guidance on the format for such a chart, the Court directs Plaintiff to review *In re NVIDIA Corp. Sec. Litig.*, 18-cv-07669-HSG, Dkt. No. 149-2.

The Court further SETS a telephonic case management conference for April 23, 2024 at 2:00 p.m. The Court further DIRECTS the parties to submit a joint case management statement by April 16, 2024. All counsel shall use the following dial-in information to access the call:

Dial-in: 888-808-6929

Passcode: 6064255

For call clarity, parties shall NOT use speaker phone or earpieces for these calls, and where at all possible, parties shall use landlines. All attorneys appearing for a telephonic case management conference are required to dial in at least 15 minutes before the hearing to check in with the CRD.

IT IS SO ORDERED.

Dated: 3/18/2024

HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California